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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT

SAN FRANCISCO DIVISION

SANDOZ INC., Plaintiff, v. AMGEN INC. and HOFFMAN-LA ROCHE INC., Defendants.	**Case No. 3:13-cv-02904-MMC** **SANDOZ INC.'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS** **REDACTED**

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STATEMENT OF THE ISSUE

Does this Court have declaratory judgment jurisdiction to resolve a dispute regarding two submarine patents Defendants acquired over two decades after their filing dates, where Defendants have taken a particular position under these patents forcing Sandoz to either abandon commercialization of its biologic product, or proceed with further investment at the risk of pursuing infringing activity?

INTRODUCTION

For over nine years, Sandoz has researched and developed a biosimilar drug to compete with Amgen's Enbrel. Sandoz engaged in its product development with the legitimate expectation that Amgen's patents covering Enbrel—first issued nearly twenty years ago—all would have expired by Sandoz's anticipated product launch in 2016. Yet, just as Amgen's patents were expiring and Sandoz's development was nearing its end, Amgen suddenly announced that the PTO had issued two brand new patents on Enbrel, allowing it to exclude all biosimilar competition until 2029. Amgen's threats under these new patents, issuing from unpublished submarine applications, have upended Sandoz's settled expectations and cast uncertainty over its product and business as a whole.

Sandoz's Complaint identifies precisely the situation the Declaratory Judgment Act was intended to address. After expending many years of effort and tens of millions of dollars, Sandoz has a final product it intends to launch upon FDA approval in three years. Amgen seeks to exclude that product based on patents Sandoz believes are invalid. Sandoz faces the present quandary that further investment—[redacted]—could be wasted if it is later found to infringe. And, unless Sandoz obtains clarity of its rights, it will be required to shelve its product or risk the potential for significant liability by launching it. Because Amgen will not license a biosimilar version of Enbrel under any circumstances, this lawsuit is Sandoz's only realistic hope to obtain clarity of its rights before its intended launch.

Amgen, by its motion, seeks to hold Sandoz's rights in limbo until Amgen decides the time is right for it to sue for infringement. To that end, Amgen argues this dispute is not sufficiently "real" or "immediate" because—so it claims—Sandoz's clinical trials might fail or cause a change in its

product design or delay its FDA filing. But these concerns are imaginary. Despite making a "factual attack" on jurisdiction, Amgen does not muster any actual evidence to support its allegations. Rather, it manufactures a list of hypothetical problems based on a collage of inadmissible hearsay snippets unrelated to the facts of the case. The only actual evidence of record—submitted herewith—demonstrates Sandoz's product is final after nearly a decade of development; it has ***already*** been successfully tested in humans; and its sole remaining clinical trial is merely confirmatory because Sandoz already established a high degree of similarity to Enbrel.

Apart from being factually baseless, Amgen's arguments directly contradict its own successful arguments in prior litigation. Twice, Amgen has sued its competitors for declaratory judgments of *future* infringement before any FDA filing had been made. Both times, the court found jurisdiction existed. *Amgen, Inc. v. F. Hoffman-LaRoche Ltd.*, 456 F. Supp. 2d 267 (D. Mass. 2006); *Amgen, Inc. v. Hoechst Marion Roussel, Inc*, 3 F. Supp. 2d 104 (D. Mass. 1998). Amgen successfully argued in the *Roche* case that "future infringement was found to be sufficiently imminent and real for purposes of declaratory relief jurisdiction under *Lang* even though ***clinical trials had not yet begun*** and approval was ***years*** away." (Ex. 1 at 13) (emphasis added). Where jurisdiction existed for Amgen to sue for a declaratory judgment in far less compelling circumstances, jurisdiction also exists for Amgen to be sued for declaratory judgment here.

Amgen also argues there is no "controversy," because it did not make specific threats against Sandoz's product in particular. Amgen is clearly wrong. Under the Supreme Court's *MedImmune* decision, specific threats of infringement are not required. Rather, a controversy exists "where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do." *SanDisk Corp. v. STMicroelectronics, Inc*., 480 F.3d 1372, 1381 (Fed. Cir. 2007). Here, Amgen has trumpeted its "exclusivity" under its new patents to the entire industry, time and again, and made clear its strategy for Enbrel depends on excluding all competition. It cannot be heard to threaten the *entirety* of its competitors, and then claim there is no "controversy" when a *particular* competitor seeks adjudication of its rights. Indeed, Amgen concedes it intends to enforce its patents against Sandoz—

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just on its own timeline. (Br. at 2). The law does not require Sandoz to wait for Amgen to sue at its leisure while Sandoz suffers from the delay.

Finally, Amgen urges this Court to exercise its discretion and dismiss the action. There is no basis to do so. Dismissing this case would frustrate the purpose of the Declaratory Judgment Act by allowing Amgen to disrupt Sandoz's settled expectations with invalid submarine patents, and then deny Sandoz the ability to determine its rights. Further, if Sandoz were forced to wait until after filing its FDA application, the lawsuit could not be [redacted] between its FDA filing and anticipated product launch. By filing now, Sandoz gives the Court adequate time to hold trial and issue judgment before Sandoz's launch rather than resolve the dispute in an emergency hearing. Maintaining this action thus advances sound judicial administration.

For all of these reasons, this court clearly has subject matter jurisdiction, and it should exercise its discretion to hear this lawsuit. Amgen's motion lacks merit and should be denied.

FACTUAL BACKGROUND

A. Amgen markets Enbrel, claiming patent exclusivity since 1995.

Enbrel is a widely used biologic drug approved by the FDA for the treatment of autoimmune conditions. (Compl. ¶¶ 14, 47; Ex. 4). Its active ingredient is a protein called etanercept, which functions to reduce inflammation in the body by binding to tumor necrosis factor (TNF). (*Id.*, ¶ 14; Ex. 4). Amgen's predecessor developed Enbrel in the early 1990s, and the FDA originally approved it in 1998 for the treatment of rheumatoid arthritis. (Compl. ¶¶ 14; Ex. 4). In 2012, Enbrel was Amgen's second largest product, accounting for 25% of its annual revenues and over $4.2 billion in North American sales. (Compl. ¶ 47; Ex. 3 at 62-63, F-22).

Ever since its approval in 1998, and before, Amgen and its predecessor have claimed that Enbrel is protected by U.S. patents. (*Id.*, ¶¶ 14-15). Among other patents, Immunex acquired U.S. Patent No. 5,395,760 in 1995 and U.S. Patent No. 5,605,690 in 1997 (Ex. 5-6), both of which Amgen listed on the package insert for Enbrel. (*Id.*, ¶ 18; Ex. 4). Based on these patents, Amgen has enjoyed exclusivity over Enbrel for fifteen years and counting. The '760 patent expired in 2012, while the '690 patent expires in 2014. (*Id.*, ¶ 19).

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B. Relying on the upcoming expiration of Amgen's patents, Sandoz develops and finalizes an etanercept product to compete with Enbrel.

Sandoz, a leading developer of generic drugs and biosimilars, began work on its own etanercept product in 2004 and has developed it continuously since that time. (Compl. ¶¶ 35-44; Jankowsky ¶¶ 2-10). Sandoz timed its development so that its commercial marketing would coincide with, or post-date, the expiration of potentially relevant patent rights, including the '760 and '690 patents. (Compl. ¶ 35; Jankowsky ¶ 16). Thus, Sandoz devoted substantial resources to ensure its product would be ready for a 2016 product launch. (Compl. ¶¶ 3, 35, 43-44; Jankowsky ¶¶ 2, 11, 16).

Sandoz's work in developing etanercept was both extensive and expensive. (Compl. ¶¶ 35-44; Jankowsky ¶¶ 2-12). Sandoz created a cell line utilizing a complex and iterative process focusing on comparable quality attributes to Enbrel obtaining a final, selected master cell-line, developed a manufacturing process and a suitable formulation of the drug, proved similarity with Enbrel on a molecular basis, developed a pre-filled syringe drug product, and transferred its processes to large scale production for clinical trials. (Compl. ¶ 36; Jankowsky ¶¶ 2-12). Working closely with the FDA, Sandoz has since tested its product in several animal models, in a Phase I clinical trial with healthy human volunteers, and now in an ongoing Phase III clinical trial. (Compl. ¶¶ 39, 41-42). The total costs, through completion of the Phase III trial, are expected to be more than [redacted]. (Compl.¶ 43).

After nine years of systematic efforts, Sandoz now has a final etanercept product. (*Id.*, ¶ 44; Jankowsky ¶ 7). Although Amgen speculates that the product may change in various ways (Br. at 13-14), Amgen is mistaken. Given how FDA regulations operate, there is no way the product could be changed in any material way at this late stage in the process, because any such change would essentially require Sandoz to start over. Sandoz's product has already been subjected to extensive validation. [redacted]

[redacted] (*Id.*). Sandoz does not intend to rewind a decade of successful development by changing its product now. (Jankowsky ¶ 7).

Likewise, Sandoz's manufacturing process is fixed. (Jankowsky ¶¶ 12-13). While Amgen points out that a manufacturing method hypothetically may change as it is scaled up (Br. at 14), Amgen fails to recognize that [redacted] (*Id.*, ¶¶ 12-13). [redacted] (*Id.*, ¶¶ 12-13, 18).

C. Sandoz will submit an FDA application for etanercept following the conclusion of a final, confirmatory Phase III trial.

The current Phase III trial is the final stage in the development of Sandoz's etanercept product. (Roth ¶¶ 8, 10). This study, which is intended to support both U.S. approval and European registration, tests the safety and efficacy of etanercept in a large population of patients suffering with plaque psoriasis, as compared to Enbrel. (*Id.* ¶ 10). [redacted].[1]

While Amgen speculates that Sandoz's Phase III clinical trial may fail in some unspecified way (Br. at 11-12), there is no reason to believe that will happen. When testing a brand new compound for the first time, establishing efficacy in a large patient population can be uncertain. But that is not the situation here. The clinical trial of a biosimilar drug does not start from a blank slate, but relies on the safety and efficacy already demonstrated by the reference biologic product in

[1] [redacted]

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treating a given condition. (Roth ¶ 14). Here, Enbrel has already been shown to work in treating psoriasis. (*Id.*). Sandoz's etanercept product has been shown to be highly similar to Enbrel on a molecular basis, which is what matters for biosimilarity. (Jankowsky ¶¶ 4-5). The same dosage form, method of administration, and strength of etanercept are being tested in Sandoz's ongoing trial. (Roth ¶ 14). Thus, the Phase III trial is simply a confirmation that Sandoz's etanercept product is similar to Enbrel, as Sandoz already demonstrated in earlier studies. (*Id.*, ¶ 14). Given the already-established identity between Sandoz's product and Enbrel, there is no good scientific basis for expecting anything other than the confirmatory trial will prove successful—just as it was for Amgen. (*Id.*, ¶ 7, 8, 10, 14-15).

Sandoz has developed and marketed three biosimilar products in Europe and one in the United States. (Roth ¶ 5). None of the Phase III studies for initial filing of these drugs failed. (*Id.* ¶ 15). [redacted] (*Id.* ¶ 16). Sandoz's 100% success rate in these late-stage trials of biosimilar products for initial filing speak volumes about the likelihood of a successful outcome here. (*Id.*). And, contrary to Amgen's baseless assertions (Br. at 3), there is no reason to believe the FDA will require additional clinical studies. Sandoz designed its Phase III study in close consultation with the FDA for the purpose of showing biosimilarity under the FDA's regulations, and understands based on those interactions that the design is adequate for assessing biosimilarity. (Roth ¶ 10-11).

Amgen posits that Sandoz's clinical trial might be delayed because it will not be able to successfully enroll patients in its clinical study (Br. at 10). [redacted] (*Id.*).

Amgen also asserts that Sandoz may not be able to assemble its regulatory dossier on time. (Br. at 12). That is nonsense. Sandoz has a capable, full time staff dedicated to regulatory affairs with extensive experience in submitting FDA applications. (Roth ¶ 18). Sandoz's regulatory group works hand-in-hand with its parent company Novartis, and thus draws on the experiences of one of

the world's largest pharmaceutical companies, which makes numerous FDA filings every year. (*Id.*). There is simply no question that Sandoz will be able to assemble the required paperwork, as it has done repeatedly in the past.

Following the conclusion of its Phase III clinical trial, Sandoz will submit an application seeking FDA approval. (Roth, ¶ 18; Jankowsky ¶ 14). [redacted] (*Id.*). In fact, the review period for Sandoz's application may be much quicker. The FDA has publicly committed to reviewing NDA and BLA applications in a period of 10 months' time. (Ex. 7). And as Amgen has explained elsewhere, the average time of FDA approval even for new biologic drugs is "likely 10 to 13 months." (Ex. 1 at 9).

D. Just as its patent position is set to expire, Amgen obtains two submarine patents allegedly covering etanercept until 2029.

While Sandoz was researching, developing, and finalizing its etanercept product in reliance on Amgen's patent expirations, Amgen was secretly prosecuting applications that would threaten to extend its monopoly on Enbrel for another seventeen years. (Compl. ¶¶ 2, 5, 26). Amgen exclusively licensed rights in two patent applications from Roche, which were filed in 1995 and based on still older applications filed in 1990. (Compl. ¶¶ 21-23, 28-31; Ex. 10 at 1; Ex. 11-12). In 2005, Amgen took over their prosecution and sought to use them as vehicles to obtain additional patents putatively covering etanercept to extend Amgen's market exclusivity. (Compl. ¶¶ 21-23, 28-31; Ex. 8-9). The applications were unpublished and unavailable to the public, and thus, Sandoz had no reason to suspect they even existed. (Compl. ¶¶ 2, 5, 35, 71).

On November 22, 2011, just as the '760 patent was expiring, Amgen issued a press release proclaiming that it had acquired U.S. Patent No. 8,063,182. (Compl. ¶ 53; Ex. 10-11). Amgen announced that "[t]he patent describes and claims the fusion protein that is etanercept, and by statute, the '182 patent has a term of 17 years from today"—until November 2028. (Ex. 10). Five months later, on April 24, 2012, the Patent Office issued U.S. Patent No. 8,163,522, based on the other submarine application. (Compl. ¶ 28; Ex. 12). Amgen claimed that the '522 patent, like the '182 patent, is "material" to its Enbrel product. (Compl. ¶ 52; Ex. 3 at 6). According to Amgen, the

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term of the '522 patent is set to expire April 24, 2029—39 years after its original application was filed. (*Id.*).

E. Amgen engages in a public campaign touting its newfound patent "exclusivity" on etanercept and threatening competition.

Following the issuance of its patents, Amgen trumpeted its newfound "exclusivity" against all biosimilar competition. For the '182 patent, Amgen announced "this newly issued patent to the fusion protein that is etanercept adds to [existing] patent protection," "we are confident in our ability to protect our products," and thus, "we do not envision Enbrel biosimilar competition in the United States for the foreseeable future." (Compl. ¶ 54; Ex. 13 at 1). At an industry conference in December 2011, Amgen proclaimed: "With a broad patent estate that we have now established for Enbrel, we feel that the market *exclusivity* for Enbrel is going to be prolonged and we don't anticipate *any biosimilar competition* in the foreseeable future." (Compl. ¶ 55; Ex. 14 at 2). Amgen sounded the same refrain over and over throughout 2012-13. (Compl. ¶¶ 53-60; Ex. 16-19, *e.g.*, Ex. 18 at 3 ("Given this added *exclusivity* that we now have on Enbrel, we are not expecting *any biosimilar competition* for Enbrel in the foreseeable future.")).

Amgen was already notorious for its aggressive patent enforcement actions. It had previously sued competitors seeking a declaration of future infringement before any FDA filings were made. (Ex. 2 at ¶¶ 27-30 Ex. 23 at 14-15). In 2012, while it was boasting about its new Enbrel patents, Amgen's CEO stated: "we have consistently demonstrated that we have the will and the skill to defend our intellectual property, and you should expect that we'll do that with respect to our G-CSF franchise as well as our other franchises." (Ex. 22 at 12). Further, he warned: "you should expect that we will assert our IP rights, and to the extent that they infringe, you should expect that we'll deal with that through the appropriate channel." (Compl. ¶ 63; Ex. 22 at 12).

Amgen's message to Sandoz and other potential biosimilar competitors is clear. The '182 and '522 patents cover Enbrel, Amgen will not tolerate biosimilar competition, and it will enforce the '182 and '522 patents to protect its market exclusivity.

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F. Amgen's patent position disrupts Sandoz's settled expectations and places it in a legal quandary.

Amgen's new patent position has disrupted Sandoz's business expectations. (Compl. ¶¶ 3-5; Jankowsky ¶¶ 16-20). Sandoz has allocated nine years of product development and [redacted] in reliance on defined patent expiration dates, only to have Amgen suddenly claim the right to exclude its product for an entire generation based on submarine patents issuing two decades after their original filing dates, which Sandoz had no way of knowing about. (*Id.*). Sandoz, however, has no intention of abandoning its product in the face of Amgen's threats. It believes the patents are invalid for multiple reasons, unenforceable, and not infringed. (Compl. ¶¶ 4, 26-27, 34, 73-108). Sandoz intends to file its FDA application at the conclusion of its clinical trials. (Compl. ¶¶ 3-4; Jankowsky ¶ 14).

Amgen's patent claims place Sandoz in an untenable situation. [redacted] Sandoz is thus faced with the present decision to proceed with activities directed towards allegedly infringing activity or abandoning them. (*Id.*).

There is no hope of Sandoz obtaining a license from Amgen. Amgen has repeatedly stated it intends to exclude biosimilar competition for Enbrel; indeed, its whole business model is premised on enforcing its patents against competing products. Amgen has grown its Enbrel sales into 25% of its company's total through price increases that would be impossible with biosimilar competition. (Compl., ¶ 48; Ex. 3; *id.* at 62- 63 (15% increase in Enbrel revenues primarily attributable to increase in sales price)). The '182 and '522 patents are thus critical to Amgen's long-term strategy for Enbrel, which stands to be even more profitable for Amgen once a co-promotion agreement with Pfizer expires later this year. (Compl. ¶ 49; Ex. 3 (Shareholder Ltr.); Ex. 14 at 2; Ex. 16 at 3; Ex. 17 at 2). Licensing the patents to Sandoz would be contrary to Amgen's entire business plan for Enbrel. (*E.g.*, Ex. 17 at 2; Ex. 3 at 44-45 (discussing risk factor of biosimilar competition)).

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Nevertheless, before filing this action, Sandoz wrote to Amgen and Roche, providing notice of its intended commercial launch, and requesting a covenant not to sue under the '182 and '522 patents. (Compl. ¶ 68; Ex. 24). Amgen and Roche have declined to grant Sandoz's requested covenant, and to date, have not responded to Sandoz's letter. Now, Amgen confirms that it intends to sue Sandoz in the future—only on its own timetable. (Br. at 2-3).

LEGAL STANDARD

Amgen seeks dismissal of this action pursuant to Rule 12(b)(1). "A Rule 12(b)(1) jurisdictional challenge may be facial or factual." *Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004). Here, Amgen makes a purported "factual attack" to Sandoz's Complaint. "[I]n a factual attack, the challenger disputes the truth of the allegations that, by themselves, would otherwise invoke federal jurisdiction." *Id.* When a factual attack is made, the plaintiff "bears the burden of establishing subject matter jurisdiction by a preponderance of the evidence." *Reynolds v. Army & Air Force Exch. Serv.*, 846 F.2d 746, 748 (Fed. Cir. 1988).

The Court considers evidence submitted by the parties on a 12(b)(1) motion in the same form, and based on the same Rules of Evidence, that it does when it considers summary judgment. Thus, "only *admissible evidence* may be considered." *Beyene v. Coleman Sec. Servs., Inc.*, 854 F.2d 1179, 1181-82 (9th Cir. 1988) (emphasis added). Unauthenticated documents, statements made without personal knowledge, and hearsay cannot be entertained. *See id.* (disregarding exhibits that contained hearsay and "lacked foundation"); *Kamen v. Am. Tel. & Tel. Co.*, 791 F.2d 1006, 1010-11 (2d Cir. 1986) ("In accord with principles of fundamental fairness and by analogy to Rule 56(e) and (f), it was improper for the district court, in ruling on the 12(b)(1) motion, to have considered the conclusory and hearsay statements contained in the affidavits submitted by defendants….").

ARGUMENT

Amgen's motion to dismiss is baseless. Its purported "factual attack" on jurisdiction is little more than a pasted-together conglomeration of hearsay snippets from various articles, blogs, and even more dubious sources. When this incompetent "evidence" is stripped away—as it must be—Amgen's principal argument is based on nothing more than its own completely unsupported and erroneous speculation that Sandoz's etanercept product might somehow, someway, be delayed or

changed. To say the least, Amgen is mistaken. The evidence of record shows that Sandoz's product is in the very final stages of development, not subject to change, and proceeding expeditiously to completion of its final clinical trial, FDA review, and approval.

Amgen's legal arguments are equally meritless. Contrary to its assertions, jurisdiction does not require Sandoz to have made an FDA filing, nor does it require Sandoz to have completed all clinical trials, nor does it require Amgen to have made particular threats to sue. Rather, the Act permits declaratory judgment actions to the greatest extent the Constitution allows—where there is an *actual controversy* between the parties of sufficient reality and immediacy to support a declaratory judgment. That is the case here.

Ultimately, Amgen seeks to dismiss this case in the hopes of bringing an infringement action in the future, at a time and place of its own choosing. The Court should decline that request. Dismissing this action would advance no rational purpose, serve only to delay adjudication of the parties' dispute to Sandoz's prejudice, and require Sandoz's rights be adjudicated in an emergency hearing, contrary to sound judicial administration.

I. The Court Has Subject Matter Jurisdiction Over This Action.

A. Jurisdiction Only Requires The Existence Of An "Actual Controversy."

The Declaratory Judgment Act provides, "[i]n a case of actual controversy," the district court "may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201. Its purpose in patent cases is "to provide the allegedly infringing party relief from uncertainty and delay regarding its legal rights." *Micron Tech. Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008). A "declaratory judgment is 'especially useful in avoiding the necessity ... of having to act at one's peril or to act on one's own interpretation of his rights, or abandon one's rights because of a fear of incurring damages.'" *Arkema Inc. v. Honeywell Intern., Inc.*, 706 F.3d 1351, 1357-58 (Fed. Cir. 2013)) (quoting S. Rep. No. 73–1005, at 2–3 (1934)).

The Act's sole requirement "is that the conflict be real and immediate, *i.e.*, that there be a true, actual 'controversy' required by the Act." *Cardinal Chem. Co. v. Morton Intern., Inc.*, 508 U.S. 83, 96 (1993) (quotation omitted). The Act thus extends to the greatest scope allowed by

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Article III of the Constitution. *Caraco Pharm. Labs, Ltd. v. Forest Labs, Inc*., 527 F.3d 1278, 1290 (Fed. Cir. 2008) ("It is well established that the phrase "actual controversy" in § 2201(a) includes any controversy over which there is Article III jurisdiction."). The Supreme Court has observed that "[m]erely the desire to avoid the threat of a 'scarecrow' patent, in Learned Hand's phrase, may therefore be sufficient to establish jurisdiction under the Declaratory Judgment Act." *Cardinal Chemical Co.*, 508 U.S. at 96.

Jurisdiction will exist where "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). Under this standard, "an 'actual controversy' requires only that a dispute be 'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical set of facts.'" *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1339 (Fed. Cir. 2007) (quoting *Medimmune*).

Although the Federal Circuit previously required DJ plaintiffs to have a "reasonable apprehension" of being sued, the Supreme Court rejected that rule in *MedImmune*, liberalizing the standard for DJ actions. *See Micron*, 518 F.3d at 902. "[T]he now more lenient legal standard facilitates or enhances the availability of declaratory judgment jurisdiction in patent cases." *Id.* After *MedImmune*, a controversy exists "where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do." *SanDisk Corp. v. ST Microelectronics, Inc*., 480 F.3d 1372, 1381 (Fed. Cir. 2007). For instance, a patentee's refusal to grant a license "suggests that there is an active and substantial controversy between the parties." *Arkema*, 706 F.3d at 1358. Likewise, a patentee's public statements about its patent position may also demonstrate the existence of a controversy. *See Micron*, 518 F.3d at 901.

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B. There Is An Actual Controversy Requiring Judicial Resolution.

The facts here establish the minimal requirements for an "actual controversy." Amgen has clearly "taken a position" that requires Sandoz to pursue allegedly infringing activity or abandon its product launch plans. *SanDisk*, 480 F.3d at 1381. It has repeatedly announced its two submarine patents give it the right to exclude all biosimilar competition from the market. Amgen's allegations force Sandoz to choose to proceed with, or abandon, substantial investments in preparing its allegedly infringing product for launch, particularly, [redacted] dollar expansion of manufacturing facilities it needs to meet the expected demand for U.S. commercialization. Further, without the present litigation, Sandoz will lack certainty of its rights, and would be faced with the choice of launching its product at the risk of a potentially devastating damages claim or give up what it believes it has a right to do. These quandaries pose the "quintessential example of a situation in which declaratory relief is warranted." *Arkema*, 706 F.3d at 1357; *City of Aurora ex rel. Aurora Water v. PS Sys., Inc.*, No. 07-CV-02371, 2008 WL 4377505, *11 (D .Colo. 2008) (DJ plaintiff's pursuit of allegedly infringing construction project put it in "the untenable position of either pursuing arguably illegal behavior or abandoning … the Project altogether, despite the millions of dollars it has invested already"—"the classic dilemma that the Declaratory Judgment Act is meant to ameliorate")

Amgen claims that its patents are "irrelevant" to Sandoz's business because Sandoz has chosen to forge ahead despite their issuance. (Br. at 21-22). But this argument misses the point. What is relevant for jurisdiction is that Amgen has placed Sandoz "***in the position*** of either pursuing arguably illegal behavior or abandoning that which [it] claims a right to do." *Sandisk*, 480 F.3d at 1381 (emphasis added). The law does not require Sandoz to make a particular decision once it is put in that position. *Id.*; *see also Alpharma, Inc. v. Purdue Pharma L.P.*, 634 F. Supp. 2d 626, 630-31 (W.D. Va. 2009) (finding jurisdiction under *Sandisk* where "plaintiff must ***either*** continue to produce a drug that is potentially encompassed by the defendant's patents ***or*** reluctantly forgo the drug's development.") (emphasis added). Indeed, if Sandoz simply gave up, Amgen would presumably claim that Sandoz lacked standing since it would no longer have a product.

Amgen suggests its submarine patents have had no effect on Sandoz because Sandoz is developing its product for European markets. Amgen is wrong. [redacted]

Amgen also halfheartedly claims there is no "controversy" between the parties because Amgen did not threaten litigation against Sandoz in particular. (Br. at 20-21). But this argument invites legal error. In *MedImmune*, the Supreme Court held a licensee could challenge a patent without first breaching the license, and thus, without the patentee first threatening suit. 549 U.S. at 128, 137. Following *MedImmune*, the Federal Circuit has repeatedly found "[a] ***specific threat*** of infringement litigation by the patentee is ***not required*** to establish jurisdiction." *ABB Inc. v. Cooper Indus., LLC*, 635 F.3d 1345, 1348 (Fed. Cir. 2011) (emphasis added); *see also Arkema*, 706 F.3d at 1358 ("***Nor is it necessary*** that a patent holder make ***specific accusations*** against either the potential direct infringers or Arkema.") (emphasis added); *Neuralstem, Inc. v. StemCells, Inc.*, 573 F. Supp. 2d 888, 894 (D. Md. 2008) (rejecting the argument that "an identification of a specific patent and the allegedly infringing products or activities" was necessary; "[T]he Federal Circuit has acknowledged that declaratory judgment jurisdiction can exist even where the potential declaratory judgment defendant cannot sue or has not indicated a willingness to sue") (citing *SanDisk* and *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271, 1284 (Fed. Cir. 2007)); *Alpharma, Inc.*, 634 F. Supp. 2d at 630-31 ("Nevermind that the defendant did not explicitly threaten the plaintiff with litigation.").

Requiring Amgen make specific threats against Sandoz would serve no rational purpose here. Amgen has already made its patent position clear to the entire industry, repeatedly, since the first submarine patent issued. (Compl. ¶¶ 53-60; Ex. 10 at 1). It has stated its claim to "exclusivity" against biosimilar competition in press releases, business journals, investor conference calls, and at numerous industry conferences, while its statements and annual reports confirm that its business

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strategy requires excluding biosimilar competition. (Ex. 10 at 1; Ex. 13; Ex. 14 at 2; Ex. 15 at 9; Ex. 16 at 2; Ex. 17 at 2; Ex. 18 at 3; Ex. 19 at 4; Ex. 3 at 44-45). It has declined to license Sandoz. (Compl. ¶¶ 67-69). It has aggressively enforced patents on its major products, including by preemptive DJ actions. (Compl. ¶ 65; Ex. 2 at ¶¶ 27-30; Ex. 23 at 14-15). Its CEO has publicly boasted about its litigation history and intention to pursue similar litigation in the future (Compl. ¶¶ 62-64; Ex. 22 at 12). In sum, Amgen leaves no doubt of its intent to enforce the '182 and '522 patents against Sandoz. And in its brief, it now confirms that it will enforce these patents and possibly others against Sandoz. (Br. at 2-3). Under these circumstances, there is a clear dispute between the parties based on Amgen's own affirmative actions. Requiring Sandoz to await a specific threat, while suffering from delay, would be a meaningless formalism contrary to case law and the purpose of the Declaratory Judgment Act.

Amgen cites *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1337 (Fed. Cir. 2008) and *Impax Labs., Inc. v. Medicis Pharm. Corp.*, No. C-08-0253, 2008 WL 1767044, *3 (N.D. Cal. 2008) for the proposition that specific threats are required to establish a controversy. In *Prasco*, however, the patent merely existed and its owner took no position on it. In *Impax*, the court found there was a real issue whether the patentee would have licensed the defendant's product had they negotiated before suit—clearly *not* the situation here. *See* 2008 WL 1767044, *1, *4.[2]

Since those cases, this Court has found a controversy existed based on a patentee's general public statements that ***anybody*** practicing certain DNA technology would infringe the patent, where the statements created a barrier to funding for a particular DJ plaintiff's product. *Aria Diagnostics, Inc. v. Sequenom, Inc.*, No. 11-06391, 2012 WL 761706, *3 (N.D. Cal. 2012); *see also Micron*, 518 F.3d at 902 (finding controversy based on "MOSAID's recent public statements and annual reports [which] confirm its intent to continue an aggressive litigation strategy."); *Neuralstem, Inc.*, 2008 WL 3929350, *6 (holding non-specific public statements by patentee, coupled with patentee's litigious

[2] In *Bridgelux, Inc. v. Cree, Inc.*, No. 06-6495, 2007 WL 2022024, *9 (N.D. Cal. 2007), which Amgen also cites, the court declined jurisdiction because the plaintiffs' basis for claiming jurisdiction was based on "hearsay or double hearsay." Moreover, that case did not involve a situation—as here—where the patent holder took a particular position about its patent covering a particular product.

history, established a controversy under the totality of the circumstances). Under all of the circumstances, the present facts fall well with the scope of the case law affirming jurisdiction.

C. The Controversy Is Real And Immediate.

Amgen argues that this case is not sufficiently "real" or "immediate" to warrant the issuance of a declaratory judgment. Again, Amgen is wrong.

1. Sandoz's product is not subject to change.

In patent cases, "the reality requirement is often related to the extent to which the technology in question is '*substantially fixed*' as opposed to 'fluid and indeterminate' at the time declaratory relief is sought." *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 882 (Fed. Cir. 2008) (citation omitted) (emphasis added). Where the technology is substantially fixed, as opposed to "in an early stage of development," the reality requirement is satisfied. *Id.*

Here, far from being "in an early stage," Sandoz's product is in the very final stage of development. It has been thoroughly validated over the course of *nine years*, shown to be identical or highly similar to Enbel in a wide array of molecular studies, tested in humans and animals, and shown to possess equivalent pharmacokinetics and safety to Amgen's Enbrel in humans. (Jankowsky ¶¶ 4-5; Roth ¶¶ 7, 9). The product cannot change without rewinding this process, which Sandoz has no intention of doing. (Jankowsky ¶ 7).

Amgen speculates that the route of administration, method of manufacture, or formulation of Sandoz's product all could change in unspecified ways (Br. at 3, 22-23). They will not. First, the route of administration for Sandoz's biosimilar product is *required by law* to be the same as Enbrel's. 42 U.S.C. § 262(k)(2)(A)(i)(IV) (requiring the "route of administration" be "the same" as "the reference product"). (Roth ¶ 17). Second, contrary to Amgen's assertions, Sandoz does not need to scale up its manufacturing process to produce drug product for clinical trials. This activity has *already occurred* (Jankowsky ¶¶ 12-13), and there is no need for the manufacturing changes Amgen imagines.[3] Third, Amgen presents no basis for its assertion that Sandoz's formulation will

[3] Amgen's argument is based on a misreading of Sandoz's Complaint. In the paragraph Amgen cites, Sandoz stated that it needs to increase its production capabilities. (¶ 43). It did not say it needed to scale up its process for clinical trials. Sandoz needs the additional facilities to perform the same scaled-up process so it can meet anticipated commercial demand, not make product for clinical studies. As to the purported "evidence" that Amgen cites regarding Genzyme's scale-up, it is blatant hearsay that is entirely irrelevant.

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change, and there is none. Even assuming a change to the formulation occurred, it would be irrelevant to the patents here, which, according to Amgen, claim "the protein that is etanercept." (Ex. 10). Sandoz's product has always been and will continue to be etanercept, regardless of any formulation changes, which it has no intention of making.[4]

This case presents a far cry from the cases Amgen cites in support of dismissal. In *Sierra Applied Scis. v. Advanced Energy Indus.*, 363 F.3d 1361, 1379 (Fed. Cir. 2004), the plaintiff presented no evidence that it even built a *prototype* of its product "until at least a year after the commencement of suit." *Cat Tech*, 528 F.3d at 881 (discussing *Sierra*). In *Benitec Austrl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1348-49 (Fed. Cir. 2007) the DJ plaintiff had only a "vaguely defined" plan to expand its "nascent" technology into veterinary products. *Id.* at 1348-49; *Cat Tech*, 528 F.3d at 881 (discussing *Benitec*). In *Teletronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992), the product in question was an original medical device that had only just begun its very first clinical trial, was not similar to any reference product (unlike a biosimilar), and thus was inherently changeable. As the Federal Circuit later explained, all of these cases presented extreme situations where the product design was "fluid and in an early stage of development." *Cat Tech*, 528 F.3d at 882.

Here, by contrast the only competent evidence is that Sandoz's etanercept product is fixed after nearly a decade of successful development, and is not subject to further change. (Jankowsky ¶¶ 2-12; Roth ¶ 16). These facts are more than sufficient to establish a "real" dispute based on a "real" product. *Cat Tech*, 528 F.3d at 882 (finding dispute was "real" where the alleged infringer "does not expect to make substantial modifications to its loading device designs").

[4] Amgen does not identify how any hypothetical change in formulation could be relevant to the patents in suit. Rather, it claims that a change may be relevant to another patent it has listed in its annual report. (Br. at 17-18). Amgen will receive discovery about Sandoz's formulation in this case, and may sue on that patent if it has a legitimate basis to do so. Sandoz submits there would be no such basis. Regardless, Amgen's uncertainty about the applicability of other patents does not detract from the Court's jurisdiction over the present dispute.

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2. Sandoz has engaged in "meaningful preparation" for allegedly infringing activity.

The "immediacy" requirement focuses on whether a party has engaged in "***meaningful preparation***" for making or using an infringing product, as compared to seeking an advisory opinion "on whether it would be liable for patent infringement if it were to initiate some merely contemplated activity." *Id.* at 881 (emphasis added). "Immediacy" does not require a present act of infringement. *Arkema*, 706 F.3d at 1356. Rather, in *Glaxo, Inc. v. Novopharm, Ltd.*, the Federal Circuit found a dispute was immediate where a generic drug manufacturer "was systematically attempting to meet the applicable regulatory requirements while preparing to import its product." 110 F.3d 1562, 1571 (Fed. Cir. 1997).

Here, Sandoz's etanercept product is no "merely contemplated activity." *Cat Tech*, 528 F.3d at 881. It has expended tremendous corporate resources, time, and effort to develop its product to a stage where it is ready for FDA submission and commercialization following a final Phase III clinical trial. (Jankowsky ¶¶ 2-11; Roth ¶¶ 8-14, 18). There is no question Sandoz has engaged in "substantial preparations," *Cat Tech*, 528 F.3d at 882, or that it has been "systematically attempting to meet the applicable regulatory requirements." *Glaxo*, 110 F.3d at 1571. Further, there is no question this dispute has immediate ramifications on Sandoz's business, based on its need to make ***present*** choices about investment in its allegedly infringing product. *See e.g., Arkema*, 706 F.3d at 1359 (finding "immediate" dispute where manufacturer was faced with "*present* position of either committing to contracts that could expose it to liability for indirect infringement or abandoning its plans" to supply infringing product")

Amgen claims this dispute lacks immediacy because Sandoz's product could "credibly fail" its clinical trial. (Br. at 11). The entire basis for this "factual attack," however, is Amgen's collection of unsworn, unauthenticated, hearsay snippets from the internet, concerning: (1) purported rates of failures of biologics in general, not biosimilars or Sandoz's biosimilars in particular (Br. at 11-12); (2) the purported difficulty in recruiting patients for a clinical trial in general (Br. at 10-11), and (3) activities of other drug companies developing other drugs that have nothing to do with

Sandoz or its product (Br. at 12). That hearsay is inadmissible.[5] *E.g.*, *Tasini v. New York Times Co., Inc.*, 184 F. Supp. 2d 350, 357 n.8 (S.D.N.Y. 2002) (stating "articles and newspaper clippings do not rise to the level of competent evidence" for 12(b)(1) motion); *3D Sys., Inc. v. Envisiontec, Inc.*, 575 F. Supp. 2d 799, 804 (E.D. Mich. 2008) ("Hearsay statements may not be considered."). The actual evidence is that Sandoz's biosimilars have never failed an initial late-stage trial, Sandoz's enrollment is ahead of schedule, and there is every reason to believe its final confirmatory trial will succeed in light of Sandoz's extensive proof of molecular and functional similarity in the analytical, bioanalytical, pre-clinical and clinical comparison with its reference product Enbrel®. (Roth ¶¶ 8-12, 14-16; Jankowsky ¶¶ 4-5, 9).

Amgen would have the Court believe no jurisdiction exists unless all clinical trials have been completed and an FDA filing has been made. (Br. at 19). But the two cases Amgen cites do not support that position. In *Teletronics*, the medical device in question—unlike here—had barely started clinical development and FDA submission was still "*years away*." 982 F.2d at 1527 (emphasis added). *Benitec* involved an equally extreme situation where "[t]he plaintiff, who sought declaratory relief in ***2005***, did not anticipate filing an NDA until '***at least 2010-2012, if ever***[.],'" *Cat Tech*, 8 F.3d at 881 (discussing *Benitec*) (emphasis added). The Federal Circuit resolved the cases on those facts, which differ dramatically from the case here, where Sandoz's product is far more advanced and will be subject to FDA approval and commercialization during the pendency of this litigation or immediately after it concludes.

Not only is Amgen's proposed rule wrong, it is directly contrary to precedent Amgen itself set during prior litigation. Previously, Amgen sued Hoechst for a DJ of future infringement despite the fact that Hoechst had not filed for FDA approval or even conducted ***any*** clinical studies of its competitive EPO drug. (Ex. 23, at ¶ 35; Ex. 1 at 13). To justify jurisdiction, Amgen relied on

[5] Sandoz specifically objects to the following purported "evidence": WD 4 (article with hearsay statement about patient enrollment); WD 8 (powerpoint slide with hearsay statement about patient enrollment); WD 9 (web article printout with hearsay statements); WD 11 (powerpoint snippet with hearsay statement about Phase III failure rate); WD 12 (corporate finance article with hearsay statements and statistics about clinical trial success rates); WD 13 (internet blog with double hearsay statements about clinical trial success rates); WD 14 (powerpoint presentation with hearsay statements about "Big pharma probability of approval"); WD 15-16 (internet blogs with hearsay about Samsung's and Teva's irrelevant product development of rituximab); WD 18 (article with hearsay about Myozyme scale-up process); WD 25 (hearsay market research about etanercept sales in Europe); WD 31 (powerpoint with hearsay about clinical development success rates).

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Glaxo, claiming that the dispute was immediate based on Hoechst's substantial preparations for infringement. (Ex. 25 at 5). The court agreed the dispute was sufficiently immediate, despite the lack of any clinical studies in that case. *Amgen, Inc. v. Hoechst Marion Roussel, Inc*, 3 F. Supp. 2d 104, 112 (D. Mass. 1998) (noting Hoechst "plans to market GA-EPO at the earliest opportunity" and there was no "question about its immediate capacity to do so upon FDA approval.").

A few years later, Amgen sued Roche for a declaratory judgment of future infringement based on Roche's development of a competitive EPO drug, claiming Roche's product, when filed, approved, and subsequently marketed in the U.S., would infringe Amgen's patents. (Ex. 2 at ¶¶ 27-31).[6] Amgen based its arguments on the same type of facts that it now disregards, including Roche's intent to market its product and its substantial preparations to do so, such as the construction of a commercial manufacturing facility. (Ex. 2, ¶ 28; Ex. 1, at 19 ("There is no doubt that Roche plans to market pegylated EPO at the earliest opportunity and that it has made meaningful commercial preparations to do so. ***These are the types of activities that courts have found to warrant exercise of declaratory relief jurisdiction***.") (emphasis added)).

In opposing a motion to dismiss for lack of jurisdiction, Amgen again cited *Glaxo*, 110 F.3d at 1571, pointing out that the Federal Circuit upheld a DJ lawsuit there, even though infringement was eighteen months away (Ex. 1 at 12). It then proceeded to rely on the precedent it set in the *Hoechst* case. Amgen argued, in direct contradiction to its current claims:

> Like *Glaxo*, this Court's application of *Lang* in *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, shows that subject matter jurisdiction exists here. Due to defendant HMR/TKT's intent and capacity to market the accused product upon FDA approval, its future infringement ***was found to be sufficiently imminent and real for purposes of declaratory relief jurisdiction*** under *Lang* ***even though clinical trials had not yet begun*** and approval was ***years away***.

(Ex. 1 at 13) (emphasis added). Relying on Amgen's arguments, the district court found jurisdiction existed and denied Roche's motion to dismiss. *Amgen, Inc. v. F. Hoffman-LaRoche Ltd.*, 456 F. Supp. 2d 267, 276-78 (D. Mass. 2006). In particular, the court found a controversy existed based on Roche's substantial preparations for infringing activity, holding Roche's expected approval date of

[6] Roche filed its FDA application well after suit was commenced.

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"***20 to 24 months away*** can be considered ***sufficiently imminent*** by this Court." *Id.* at 278 (emphasis added).

On a later appeal, there was no hint the Federal Circuit perceived a jurisdictional defect. *See Amgen Inc. v. F. Hoffman-La Roche Ltd*., 580 F.3d 1340, 1346 (Fed. Cir. 2009). This is significant because, as Amgen concedes in its brief (Br. at 6 & n.2), the Federal Circuit will dismiss a case where subject matter jurisdiction is lacking, even when the parties do not raise jurisdiction as an issue. Thus, contrary to Amgen's misstatements (Br. at 19), the "hard truth" is that the Federal Circuit has indeed upheld jurisdiction over a declaratory judgment action brought prior to an FDA filing. The court did so in Amgen's own case involving its most prominent product.

If Amgen can sue for future infringement based on a competitor's substantial preparations to market a competitive product, it is equally true that Amgen is subject to suit here. The Federal Circuit has explained: "It logically follows that if such an action creates a justiciable controversy for one party, the same action should create a justiciable declaratory judgment controversy for the opposing party." *Teva Pharmaceuticals*, 482 F.3d at 1342. For declaratory judgments, what is sauce for the goose is sauce for the gander.

Indeed, the facts are more compelling here than the prior *Amgen* cases. The prior *Amgen* cases involved situations where a patentee sued preemptively for future infringement against products undergoing development. Such lawsuits disturb the policies behind the statutory safe harbor, which insulates research related to FDA filings from infringement liability, and protects biosimilar and generic manufacturers from unwanted patent suits.[7] *See* 35 U.S.C. § 271(e)(1). No such policy is implicated when an accused infringer—as here—seeks a declaration of its *own* rights prior to FDA approval. As the court noted in *Infinitech, Inc. v. Vitrophage, Inc*., "The patent holder loses nothing by waiting, as the alleged infringer cannot market the product until gaining government approval," while "the alleged infringer has ***everything to lose*** by being forced to shelve its declaratory judgment suit until after its product receives federal approval." 842 F. Supp. 332, 337 (N.D. Ill. 1994) (emphasis added).

[7] Based on this policy, the *Hoechst* court declined to exercise its jurisdiction, despite finding an actual controversy existed. 3 F. Supp. 2d at 112.

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As in the *Amgen* cases, the *Infinitech* court found there was jurisdiction for an accused infringer's DJ action, even though FDA approval for the product was still in the future. The Court's holding describes the situation here perfectly: "While [Sandoz] may not have the present ability to market [etanercept]," the court noted, "it has embarked upon a protracted and costly process of obtaining regulatory approval." *Id.* "[Sandoz's] conduct thus evinces the kind of 'concrete steps' or 'meaningful preparation' needed to establish an actual controversy under 'all the circumstances.'" *Id.* at 337-38.

II. The Court Should Exercise Its Jurisdiction

The only remaining question is whether this Court should exercise its jurisdiction. It should. "When there is an actual controversy and thus jurisdiction, the exercise of that jurisdiction is discretionary." *Cat Tech*, 528 F.3d at 883. But that discretion, though "broad," is "not absolute." *Micron*, 518 F.3d at 903. "When there is an actual controversy and a declaratory judgment would settle the legal relations in dispute and afford relief from uncertainty or insecurity, in the usual circumstance the declaratory judgment is not subject to dismissal." *Genentech v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993). Thus, where "resolving the case serves the objectives for which the Declaratory Judgment Act was created," the Court should exercise its discretion and retain the case. *Cat Tech*, 528 F.3d at 883; *Amgen v. Roche*, 456 F. Supp. 2d at 278 ("Given that the test for the existence of an actual controversy is satisfied, the Court is warranted in exercising jurisdiction over this declaratory judgment action.").

The Act was tailor-made for a case like this. Maintaining the case stands to provide Sandoz with "relief from uncertainty and delay regarding its legal rights," and thus, would place it in the position it reasonably expected prior to Amgen's acquisition and trumpeting of its submarine patents. *Micron*, 518 F.3d at 902. Dismissing the case, on the other hand, would obstruct this objective by allowing Amgen to upset Sandoz's legitimate business expectations with invalid patents issuing over two decades after their original filing dates, dissuading Sandoz's legitimate competition and investment, while depriving Sandoz of the ability to determine its rights.

Amgen suggests that accepting this case would cause "litigation floodgates" to be opened, because it would allow DJ actions where the plaintiff was not explicitly threatened with suit. (Br. at

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23). That is not a concern here. First, the Supreme Court already rejected the explicit threat requirement. Accepting this case is entirely consistent with the Supreme Court's precedent and would not pave new ground. *See Micron*, 518 F.3d at 902 (discussing the "ease of achieving declaratory judgment jurisdiction in patent cases" following *MedImmune*). Second, the facts of this case show an undeniable dispute. Amgen has taken an express position about its patent coverage that puts Sandoz in the typical quandary implicating the Declaratory Judgment Act. Beyond that, Amgen refuses to license Sandoz and effectively admits that it will sue Sandoz for its etanercept product later if this case is dismissed. The question is not whether the dispute will be resolved in court, but *when*.

Amgen argues this case should await Sandoz's FDA filing because the Hatch-Waxman Act and the BPCIA supposedly reflect a Congressional intention to delay patent litigation until after FDA filings are made. If this statement were true, however, there would be statutory provisions confirming it. Tellingly, however, Amgen cites no provision in either statute purporting to deprive the federal courts of subject matter jurisdiction where a case or controversy is already established prior to the time of an FDA filing. There is none.

On the contrary, a declaratory judgment action is necessary to achieve patent certainty prior to Sandoz's commercial marketing. Here, all regulatory exclusivities for Enbrel have already expired. Thus, Sandoz can market its etanercept product immediately upon FDA approval, which could occur in as little as 10-12 months after its filing. Because a complex biologics patent case cannot be resolved in 10-12 months or even twice that long, the ***only way*** for the parties to achieve patent certainty prior to commercial marketing in this case is through a DJ action brought prior to the biosimilars filing.[8]

[8] The BPCIA, which governs biosimilar filings, does not allow the FDA to stay approval of a biosimilar product pending the outcome of patent litigation. Rather, in the typical case, patent issues will be resolved during a lengthy period of regulatory exclusivity the BPCIA provides for the reference biologic drug. For new BLA filings, the BPCIA provides a 4-year exclusivity period in which the FDA may not accept biosimilar applications and a 12-year data exclusivity period in which the FDA may not approve a biosimilar. 42 U.S.C. § 262(k)(7)(A)-(B). Thus, the BPCIA envisions a period of time of up to 8 years in which patent disputes can be resolved in the typical case. These exclusivities are calculated as of the date the reference product's BLA is filed. *Id.* Since the BLA for Enbrel was filed over 12 years ago, Enbrel is not entitled to ***any*** such regulatory exclusivity, and thus, the typical period for resolving patent disputes under BPCIA does not exist here.

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Achieving patent certainty prior to commercial marketing is a necessity. During the Congressional debate on biosimilars legislation, for example, Jeffrey Kushan, partner at Amgen's counsel Sidley Austin LLP, testified "any legislation ***must*** include a balanced and fair procedure for identifying and resolving patent disputes implicated by the structure of a biosimilar product and how it is made ***before the biosimilar product is approved and put on the market***." [9] Indeed, "[n]early ***all stakeholders agree*** that doing so is better for patients, caregivers, and ***both innovator and biosimilar companies***." To achieve that goal, other witnesses explained, "[w]e need things like declaratory judgment actions being available to the follow-on applicant."[10] And consistent with this goal, the BPCIA provides DJ actions can be filed by either party upon the biosimilar manufacturer's notice of commercial marketing, which Sandoz has given here. *See* 42 U.S.C. § 262(l)(8)-(9). (Ex. 24).[11] This action is thus entirely consistent with the text and the policy of the BPCIA.

If this lawsuit had to await a formal FDA filing, as Amgen suggests, it simply could not be resolved prior to the intended 2016 launch of Sandoz's product. Previously, Amgen agreed that courts should accept jurisdiction for precisely this reason. In the *Roche* litigation, Amgen vigorously urged the court to hear its case because it otherwise could not be resolved by the time of anticipated commercial marketing. (Ex. 1 at 1, 4, 15-16; *id.* at 15 (arguing "[i]f this case is not allowed to

[9] Biologics and Biosimilars: Balancing Incentives for Innovation, Hearing Before the Subcomm. On Courts and Competition Policy of the H. Comm. On the Judiciary, 111th Cong. (2009) at 46, available at http://judiciary.house.gov/hearings/printers/111th/111-73_51014.PDF (emphasis added). Mr. Kushan testified on behalf of Biotechnology Industry Organization, which represents the rights of BLA holders such as Amgen.

[10] *Id.* at 222 (statement of Teresa Stanek Rea on behalf of the American Intellectual Property Law Association in response to the question "what is the ***best way*** to resolve a patent dispute in a world that involves biosimilar competition") (emphasis added).

[11] Debate on the biosimilars legislation confirmed that Congress recognized at least three years' time would be needed to resolve DJ actions in complex biologics cases in advance of commercial marketing. In a draft of legislation subject to debate in the House, the bill provided a declaratory judgment procedure that was only available where the action was filed *less* than three years prior to commercial launch. This provision was widely criticized during Congressional hearings and ultimately removed from the House bill. *See id.* at 205 (statement of Teresa Stanek Rea)_("The assumption that a patent infringement litigation can be resolved in 3 years may not necessarily hold true."); *id*. at 35 (December 22, 2008 Letter from Bruce A. Leicher of Momenta to the Federal Trade Commission) ("As proposed at the Roundtable, one would anticipate litigation lasting four (4) years in a biologic patent."); *id*. at 21 ("Because this would not provide sufficient time to complete litigation, it would extend biologic entry well beyond the 12-14 years data exclusivity period in the bill."). In the Senate bill, which largely reflects the final statutory language, there was never any temporal limitation on DJ actions.

proceed now, there is *little likelihood that Amgen could obtain adjudication* of its infringement claims *before market entry*") (emphasis added)). And with good reason. The entire point of the DJ Act, as Amgen explained, is "to provide relief to entities at a legal risk from an unresolved dispute," "especially when the other party wishes to delay the litigation." (Ex. 1 at 11) (citing *Capo, Inc. v. Dioptics Med. Prods.*, 387 F.3d 1352, 1355 (Fed. Cir. 2004)). It makes absolutely no sense to delay the start of a DJ action to a time that no longer fulfills its appointed purpose.

Yet that is precisely the result Amgen seeks here. Perhaps Amgen hopes, given its patent threat, Sandoz will not make the substantial investments needed to effectively compete with Amgen upon its 2016 commercial launch. Perhaps Amgen hopes that Sandoz will refrain from launching its product until the case is resolved, for fear of incurring a potential damages claim. In either situation, Amgen will have extracted an unjustified benefit by holding Sandoz's rights unresolved. This action is necessary and appropriate to relieve Sandoz from this potential prejudice.

Finally, maintaining this case is appropriate for practical reasons. If this case were delayed until an FDA filing, the court would have to resolve the parties' rights in a preliminary injunction hearing prior to Sandoz's intended product launch without the benefit of a full record or completed discovery. Accepting jurisdiction now avoids the need for an emergency hearing, permits normal case management and discovery, and therefore promotes sound judicial administration. It is also consistent with a wealth of judicial experience under the Hatch-Waxman act, where courts routinely schedule trials to allow for patent issues to be resolved prior to the conclusion of the regulatory stay and intended product launch. *E.g., Shire LLC v. Amneal Pharm., LLC*, No. 11-3781, 2013 WL 1932927, *7 (D. N.J. 2013) (striking supplemental expert report where the effect of the report would "disrupt this litigation" by preventing the case from being concluded before 30-month stay expired); *Cephalon, Inc. v. Impax Lab., Inc.*, No. 11-1152, 2012 WL 3867568, *2 (D. Del. 2012) (denying stay request because "the court could not resolve the present dispute within thirty months if the remaining claims are stayed").

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CONCLUSION

For all of these reasons, Defendants' motion should be denied.

Dated: September 13, 2013

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